This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 46-R-0002
CUSTOMER NUMBER: 1561

FORM APPROVED
OMB NO. 0579-0036

South Dakota State University
Admin 130
Brookings, SD 57007

Telephone: (605) -688-4181

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (**Attach additional sheets if necessary or use APHIS Form 7023A**)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					-
5. Cats					-
6. Guinea Pigs					-
7. Hamsters					-
8. Rabbits			30		30
9. Non-human Primates					-
10. Sheep		20	31		51
11. Pigs		27	20	94	141
12. Other Farm Animals					
13. Other Animals					
Deer (muntjac)		12	2		14
Deer (whitetail)		108	20		128
Mountain lion		6			6

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE OF C (b)(6),(b)(7)(c)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (*Type or Print*) (b)(6),(b)(7)(c)

DATE SIGNED 1-29-2009

APHIS FORM 7023 (Replaces VS Form 19-23 (OCT 90), which is obsolete.)
(AUG 91)

Column E Explanation

1. Registration Number: **46-R-0002**
2. Number of animals used in this study: **19**
3. Species of animals used in the study: **Pigs (swine)**

4. Procedures: **Piglets are challenged orally with Shiga-like toxin producing *E-coli* bacteria, with blood draws at set intervals. Animals are observed at least every 4 hours for signs of the disease. Animals that reach irreversible lateral recumbency are immediately euthanized. Necropsies are used to confirm histopathologic changes in all infected animals.**

5. Scientific justification why pain and/or distress could not be relieved: **The purpose of the study is to test the efficacy of a monoclonal antibody specific to Shiga-like toxin 2 (Stx2). Pigs are the only other species other than humans that are naturally susceptible to the systematic effects of Shiga-like toxin producing *E-coli* strains.**

 Efficacy of the treatment under investigation to prevent Shiga Toxin from causing life-threatening illness in the host is evaluated based largely on behavioral observations in the experimental animal. Such observations are essential as histological lesions vary considerably and lesion differences between subjects that do not exhibit illness and those that succumb to challenge are sometimes minimal. Drugs that mitigate pain alter animal behavior and obscure subtle changes used to monitor course of disease.

6. What, if any federal regulations require this procedure? **N/A**

Column E Explanation

1. Registration Number: **46-R-0002**
2. Number of animals used in this study: **16**
3. Species of animals used in the study: **Pigs (swine)**

4. Procedures: **16 piglets, divided into 4 groups, are challenged with wild-type *Vibrio Cholerae* (C6706) and/or an isogenic regulatory mutant. Pigs are examined three times daily for signs of disease. Pigs that become recumbent are immediately euthanized. Necropsies performed to determine intestinal colonization.**

5. Scientific justification why pain and/or distress could not be relieved: **The pig model used to study *V.Cholerae* is the only model that reproduces human-like symptoms; the mouse model currently used does not. Animals must be determined to be infected and the use of pain relieving drug would mask symptoms and thus make evaluation impossible. Giving anti-inflammatories or other medications to alleviate clinical signs could also inhibit bacterial colonization.**

6. What, if any federal regulations require this procedure? **N/A**

NOV 28

Column E Explanation

1. Registration Number: **46-R-0002**
2. Number of animals used in this study: **29**
3. Species of animals used in the study: **Pigs (swine)**

4. Procedures: **Piglets are given an oral dose of Shiga-like toxin (Stx) producing e-coli. This produces clinical symptoms of diarrhea, CNS disease and/or hemologic-ueremic syndrome. Pigs are examined every four hours for signs of disease, and to monitor its progression. Pigs that become recumbent are immediately euthanized.**

5. Scientific justification why pain and/or distress could not be relieved: **The pig model used is the only model that reproduces human-like symptoms. Pain and distress cannot be relieved because giving anti-inflammatories or anti-diarrheal medications could interfere with the serum concentration of Stx.**

6. What, if any federal regulations require this procedure? **N/A**

NOV 28 2

Column E Explanation

1. Registration Number: **46-R-0002**
2. Number of animals used in this study: **10**
3. Species of animals used in the study: **Pigs (swine)**

4. Procedures: **To study the bacterial virulence of *E-coli* O157:H7, piglets are inoculated at 24 hours of age with *E-coli*. Pigs are observed at least every four hours for signs of disease progression. Pigs that become recumbent are immediately euthanized. Blood samples are taken prior to the challenge and necropsies will determine extent of intestinal colonization.**

5. Scientific justification why pain and/or distress could not be relieved: **Other (smaller) animals do not appropriately colonize *E-coli* in their intestines. Clinical signs must be observed to help confirm the presence of the disease.**

6. What, if any federal regulations require this procedure? **N/A**

NOV 28 20

Column E Explanation

1. Registration Number: **46-R-0002**
2. Number of animals used in this study: **20**
3. Species of animals used in the study: **Pigs (swine)**

4. Procedures: **Piglets are divided into treatment groups and challenged with various strains of enterotoxic *E-coli* (ETEC). Pigs are examined every four hours for signs of disease progression. Pigs that become recumbent are immediately euthanized, and all pigs euthanized 18 hours following the challenge. Blood samples are taken prior to the challenge and necropsies will determine extent of intestinal colonization.**

5. Scientific justification why pain and/or distress could not be relieved: **Assessment of the organism cannot be made using in vitro methods, or when using drugs that mask symptoms. Other (smaller) animals do not appropriately colonize *E-coli* in their intestines. Symptom relieving agents that alleviate clinical signs could inhibit intestinal colonization.**

6. What, if any federal regulations require this procedure? **N/A**

NOV 28 20